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EndoGator Advantage Irrigation Pump EGA-500

510(k) Summary

Manufacturer:	Medivators (formerly Byrne Medical, A Minntech Corporation Business Group)
Address:	3150 Pollok Dr. Conroe, TX 77303 USA
Official Contact:	Brent Geiger, MS, RAC International RA Manager bgeiger@minntech.com 763-553-3345

Trade Name:	EndoGator Advantage Irrigation Pump EGA-500
Common Name:	Endoscopic Irrigation Pump
Classification Name:	Endoscopic Irrigation/Suction System
Product Code:	OCX, Gastroenterology/Urology
Device Class:	II
Regulation No.:	876.1500
Date Prepared:	April 23, 2012
Predicate Devices:	Byrne Medical EndoGator Pump Model EGP-100 K060962 Olympus AFU-100 Irrigation Pump K073207

Medivators has provided the following information to the U.S. Food and Drug Administration to support the substantial equivalence determination of the subject EndoGator Advantage Irrigation Pump EGA-500 to the predicate EndoGator EGP-100 and Olympus AFU-100 irrigation pumps currently cleared for commercial distribution in the United States.

Device Description

The EndoGator Advantage Irrigation Pump EGA-500 is the second generation development of the current Byrne Medical EGP-100 Irrigation Pump. The EndoGator Advantage provides for a slightly higher flow rate of endoscope irrigation water and contains an attached water bottle heater to afford the clinician the option of performing water irrigation with warmed water as compared to room temperature.

The EndoGator Advantage Irrigation Pump works by turning a peristaltic roller pump head to move liquid through a tube set and into an endoscope system. The pump head will not operate if the pump head is open, and will cease to operate if the pump head is opened while the motor is activated. The unit incorporates a "Prime" feature which allows the unit to operate for a predetermined period of time.

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The device includes a water bottle warming cradle that is intended to maintain a bottle of sterile water for irrigation at a target temperature of 37°C with a tolerance of ±3°C. The water bottle heating element is attached to the underside of the aluminum cradle which then conducts heat through the bottle to warm the water. The heating element is controlled by dual temperature sensors for redundancy and safety.

Indications for Use

The EndoGator Advantage Irrigation Pump EGA-500 is indicated for endoscopic irrigation for use with washing catheters, integral endoscope water jet channels and endoscope working channels.

Comparison to Other Devices in Commercial Distribution in the United States

The EndoGator Advantage Irrigation Pump has equivalent indications for use as the predicate devices. All devices have the same intended performance and use the same method of sterile water irrigation during GI endoscopy procedures. The primary difference between the subject and predicate devices is that the subject device contains a water bottle warming cradle that is intended to maintain a sterile water bottle for endoscopic irrigation at a target temperature of 37°C with a tolerance of ±3°C. Any additional risks presented by the added water warming feature on the subject device are acceptable because it is simply being used to introduce water that is heated to approximately the same temperature as the surrounding tissues in gastro-intestinal (GI) tract.

Summary of Non-Clinical Performance Data

Medivators has performed bench testing to support the substantial equivalence of the EndoGator Advantage Irrigation Pump to the predicate EndoGator EGP-100 and Olympus AFU-100 irrigation pumps currently cleared for commercial distribution in the United States. The following types of data were provided to FDA to support substantial equivalence and demonstrate that the device performs consistently, reliably and safely as intended:

- Flow and pressure comparison
- Water temperature consistency and distribution
- Pump performance
- Heater performance
- Simulated-use
- Risk analysis
- Electrical safety IEC 60601-1
- Electromagnetic compatibility IEC 60601-1-2

Conclusion

Medivators has provided the appropriate premarket notification and supporting safety and performance information in the form of a 510(k) submission. Based on the information provided, we believe that the EndoGator Advantage Irrigation Pump EGA-500 is substantially equivalent to the Byrne Medical EndoGator Pump Model EGP-100 and Olympus AFU-100 Irrigation Pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Brent Geiger, MS, RAC
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Minntech Corporation
14605 28th Avenue North
MINNEAPOLIS MN 55442

APR 2 7 2012

Re: K113119
Trade/Device Name: EndoGator Advantage Irrigation Pump Model EGA-500
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX
Dated: March 21, 2012
Received: March 22, 2012

Dear Mr. Geiger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) number (if known): **K113119**

Device Name: **EndoGator Advantage Irrigation Pump EGA-500**

Indications for Use:

The EndoGator Advantage Irrigation Pump is indicated for endoscopic irrigation for use with washing catheters, integral endoscope water jet channels and endoscope working channels.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use_____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113119